# **Complete Summary**

## **GUIDELINE TITLE**

Adult diabetes clinical practice guidelines.

# BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente Care Management Institute. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente Care Management Institute; 2005 Dec. 206 p. [127 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Kaiser Permanente Care Management Institute. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente Care Management Institute; 2004 Mar. 167 p.

To keep current with changing medical practices, all guidelines are reviewed, and if appropriate, revised at least every two years.

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

## SCOPE

## DISEASE/CONDITION(S)

Diabetes, including:

**DISCLAIMER** 

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

## **GUIDELINE CATEGORY**

Management Prevention Treatment

## CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Pharmacology
Preventive Medicine

#### INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Dietitians Nurses Pharmacists Physician Assistants Physicians

# GUIDELINE OBJECTIVE(S)

To provide recommendations (evidence-based and consensus) on the prevention, treatment, and management of diabetes

## TARGET POPULATION

Adults with diabetes

Patients younger than 18 years old are not included.

## INTERVENTIONS AND PRACTICES CONSIDERED

## Prevention/Screening

- 1. Interventions to delay the onset of Type 2 diabetes
  - Lifestyle interventions (healthy eating; increased physical activity)
  - Drug therapy intervention (metformin)
- 2. Postpartum follow-up of gestational diabetes mellitus to prevent future progression to type 2 diabetes
  - Lifestyle interventions (weight control; lifestyle advice; patient education on increased risk)
- 3. Screening for type 2 diabetes with fasting plasma glucose

Note: Guideline developers considered but did not recommend glycosylated hemoglobin (HbA1c) as a routine screening test.

## Treatment/Management

- 1. Management of hypertension in patients with diabetes
  - Lifestyle interventions
  - Drug therapy (monotherapy and combination therapy), including thiazide diuretics, angiotensin-converting enzyme (ACE) inhibitors, beta-blocker, angiotensin receptor blockers (ARBs)
- 2. Drug therapy (ACE inhibitors or ARBs) for microalbuminuria in normotensive patients with diabetes
- 3. Lipid management in patients with diabetes (statin therapy)
- 4. Drug therapy for the primary and secondary prevention of cardiovascular disease (CVD) events in patients with diabetes (ACE inhibitor, aspirin, beta blocker, multifactorial interventions)
- 5. Management of blood glucose with intensive glycemic control (metformin as first line glucose lowering drug, step therapy, individualized HbA1c target)
- 6. Monitoring microalbumin in patients with diabetes and documented microalbuminuria
- 7. Screening for retinopathy
- 8. Foot screening with monofilament test
- 9. Self-management, including education and training in self-care behaviors and self monitoring of blood glucose

## MAJOR OUTCOMES CONSIDERED

- Timing of onset and incidence of diabetes and diabetes complications
- Functional/health status
- Quality of life
- Rates of hospitalization
- Rates of office visits
- Development of or progression to glycosylated hemoglobin (HbA1c/GHb)
- Morbidity and mortality related to diabetes

## METHODOLOGY

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Guidelines are developed using an "evidence-based methodology" and involve a systematic literature search, critical appraisal of the research design and statistical results of relevant studies, and grading of the sufficiency (quantity, quality, consistency, and relevancy) of the evidence for drawing conclusions.

During the guideline development process, the Guideline Development Team reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines, and consensus-based statements from external professional societies and government health organizations, and clinical expert opinion of Kaiser Permanente regional specialty groups.

For details of the literature search, including databases searched and search terms for each clinical question, see the original guideline document.

## NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Refer to Table 2 in the Appendix in the original guideline document for the system for grading the strength of a body of evidence.

## METHODS USED TO ANALYZE THE EVI DENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Guidelines Project Management Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

To develop the Adult Diabetes Guideline, released in January 2006, a multidisciplinary, interregional Guideline Development Team first met in July 2005 to define the scope of the guideline. The Project Management Team then performed systematic reviews of the medical literature on each of the clinical questions identified by the Guideline Development Team, assembled the evidence, and developed draft recommendations for review by the Guideline Development Team. All of the recommendations and supporting evidence were reviewed by the Guideline Development Team in depth through a series of conference calls in October through December 2005.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are classified as either "evidence-based (A-D, I)" or "consensus." Refer to the table below for full definitions.

- Evidence-based: sufficient number of high-quality studies from which to draw a conclusion, and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered "evidence-based" if there is insufficient evidence and no practice is recommended.
- Consensus: insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team.

# Label and Language of Recommendations\*

| Label                  | Evidence-Based Recommendations  |
|------------------------|---|
| Evidence-<br>based (A) | Language: <sup>a</sup> The intervention is strongly recommended for eligible patients.  |
|                        | Evidence: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs.   |
|                        | Evidence Grade: Good.   |
| Evidence-<br>based (B) | Language: <sup>a</sup> The intervention is recommended for eligible patients.   |
|                        | Evidence: The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs.  |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (C) | Language: <sup>a</sup> No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.)  |
|                        | Evidence: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (D) | Language: <sup>a</sup> Recommendation against routinely providing the intervention to eligible patients.  |
|                        | Evidence: The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits.  |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (I) | Language: <sup>a</sup> The evidence is insufficient to recommend for or against routinely providing the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must   |

| Label               | Evidence-Based Recommendations  |
|---------------------|---|
|                     | list all the equivalent options.)   |
|                     | Evidence: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.   |
|                     | Evidence Grade: Insufficient.   |
| Consensus-<br>based | Language: <sup>a</sup> The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors.   |
|                     | Evidence: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. |
|                     | Evidence Grade: Insufficient, unless otherwise stated.  |

For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the evidence were good or fair, the recommendation would usually be evidence-based. In this kind of consensus-based recommendation, the evidence grade should point this out, e.g., "Evidence Grade: Good, supporting a different recommendation."

## COST ANALYSIS

- A cost/benefit analysis related to risk of gastrointestinal (GI) bleed due to aspirin in patients with diabetes demonstrated that the costs of complications, related to the adverse effects of GI bleed, exceeded benefit for patient with a 5-year coronary artery disease (CAD) risk of 4%.
- A cost/benefit analysis using generic pricing for metformin compared to conventional therapy revealed that the use of metformin was cost saving in overweight, middle-aged patients with type 2 diabetes.
- Cost/utility analysis of screening intervals cite that it may not be warranted to perform annual retinal screening on all patients without previously detected retinopathy with type 2 diabetes. Tailoring recommended intervals based on individual circumstances may be preferable.
- In the 2005 search, one cost-effectiveness analysis was found of the lifestyle modification program used in the Diabetes Prevention Program. The Archimedes model found that the expected 30-year cost/quality adjusted life

<sup>[</sup>a] All statements specify the population for which the recommendation is intended.

<sup>\*</sup> Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

year (QALY) of the DPP lifestyle intervention compared with doing nothing would be \$143,000. Using metformin to prevent diabetes would be more cost-effective, costing about \$35,400 per QALY gained. However, metformin would deliver about one third the long-term health benefits achieved by immediate lifestyle modification. This suggests that while lifestyle modification should be recommended for high-risk people, the specific lifestyle modification program used in the DPP study may not be cost effective for a national program to implement.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Guideline Directors' Guideline Quality Committee reviewed and approved the guidelines in December 2005.

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Recommendations are identified as either "evidence-based (A-D, I)" or "consensus." For definitions of the levels of recommendations see the end of the "Major Recommendations" field.

## Summary of Revisions to the 2006 Adult Diabetes Guidelines

<u>Prevention of Diabetes</u>: The Diabetes Guideline Development Team revised these recommendations to clarify that drug therapy with metformin for prevention of type 2 diabetes should only be prescribed after lifestyle intervention has been attempted.

Management of Hypertension in Patients with Diabetes: The Diabetes Guideline Development Team added combination therapy of hydrochlorothiazide/angiotensin converting enzyme inhibitors (HCTZ/ACE inhibitors) as a first-line option in the treatment of hypertension in patients with diabetes. Combination therapy of hydrochlorothiazide/ACE inhibitors was also clarified to be "recommended" when blood pressure (BP) is more than 20/10 mmHg to 30/10 mmHg above goal.

<u>Drug Therapy for Microalbuminuria in Normotensive Patients</u>: There was no evidence found which altered the previous recommendation. However, the Diabetes Guideline Development Team added a consensus-based statement recommending that angiotensin II blockers (ARBs) may be substituted for the treatment of microalbuminuria if the patient is intolerant to ACE inhibitors.

<u>Lipid Management in Patients with Diabetes</u>: The Diabetes Guidelines Development Team adopted the work of the Kaiser Permanente (KP) National Dyslipidemia guidelines for these recommendations. The most substantive revision was a consensus-based recommendation for a recommended low-density lipoprotein (LDL) target of <100 for patients age >40 with diabetes, and an optional LDL target of <70 for patients age >40 with diabetes and coronary artery disease (CAD).

<u>Drug Therapy for the Primary and Secondary Prevention of Cardiovascular Disease</u> (CVD) Events in Patients with Diabetes:

- The recommendations for aspirin for patients with diabetes were revised to include a minimum age (>40 years old) and to indicate an aspirin dose readily available in the United States (81 mg/day). Contraindications for aspirin (aspirin allergy, bleeding tendency, recent gastrointestinal bleeding, age >85, and clinically active hepatic disease) were also clarified.
- There was no new evidence found regarding beta-blocker treatment. However, based on existing evidence, the group decided to focus on those patients with diabetes, CVD, and who have had a myocardial infarction (MI), and recommend beta-blocker therapy for this group. For those patients with CVD and diabetes but no history of MI beta-blockers remain an option.

# Management of Blood Glucose:

- The Diabetes Guideline Development Team added an additional clinical question regarding the optimal medication combination for those patients who fail to reach goals on monotherapy. More than one medication is often needed to achieve goals; however, there is insufficient evidence to recommend an optimal medication combination for type 2 diabetes which is not controlled with a single agent.
- The overall treatment goal for glycosylated hemoglobin (HbA1c) is <7%. The Diabetes Guideline Development Team added more direct guidance on individualizing these goals based on shared decision-making.

## **Guidelines Summary**

- I. Prevention of Diabetes
  - A. Intervention to Delay the Onset of Type 2 Diabetes

In patients with impaired glucose tolerance (IGT) or impaired fasting glucose (IFG),\* methods to promote healthy eating and increase physical activity, which are targeted to achieve a sustained weight loss (5 to 7%), delayed the onset of diabetes and are strongly recommended as first-line therapy. If therapy goals are not achieved in a reasonable time frame through lifestyle interventions alone, the evidence supports the option of adding drug therapy with metformin. Evidence-based (A)

\*Included studies defined impaired glucose tolerance as a glucose level of 140 to 199 post 75 g glucose load. The American Diabetes Association (ADA) defines impaired fasting glucose as fasting plasma glucose (FPG) levels  $\geq$ 100 mg/dL (5.6 mmol/L) but <126 mg/dL (7.0 mmol/L).

Consensus-based

B. Postpartum Follow-Up of Gestational Diabetes Mellitus (GDM) to Prevent Future Progression to Type 2 Diabetes

In women with GDM, long-term postpartum follow-up including weight control and lifestyle advice is recommended to prevent future progression to type 2 diabetes. Patients with GDM should be educated on their higher risk of developing type 2 diabetes after delivery. Consensus-based

## II. Screening

- A. Candidates for Screening for Type 2 Diabetes
  - Screening for type 2 diabetes in patients with hyperlipidemia (LDL >130) and hypertension (defined as a blood pressure ≥140/90 mmHg) is recommended regardless of age.
  - There is insufficient evidence for screening patients with other risk factors.\*
    - Screening for these patients is optional.
  - There is insufficient evidence to recommend an optimal screening interval. Regions are encouraged to set appropriate screening intervals.

Consensus-based

- B. \* Risk factors are defined as a family history of type 2 diabetes in first- and second-degree relatives; belonging to a certain racial/ethnic group (Native Americans, African Americans, Hispanic Americans, Asians/South Pacific Islanders); or body mass index (BMI) ≥25kg/m²; or having signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, or polycystic ovary syndrome).
- B. Test to Screen for Impaired Glucose Tolerance

If a test for impaired glucose control is desired, a fasting plasma glucose (FPG) is the recommended test. HbA1c should not be used as a routine screening test.

Consensus-based

- III. Pharmacological Management of Diabetes
  - A. Management of Hypertension in Patients with Diabetes

Blood pressure threshold to initiate drug therapy in patients with diabetes and hypertension

Initiate antihypertensive therapy in patients with diabetes with a systolic blood pressure (BP) of  $\geq$ 140 mmHg and/or diastolic  $\geq$ 85-90 mmHg. After three months of lifestyle therapy, if systolic BP is 130 to 139 or diastolic BP is 80 to 89, initiate drug therapy. Consensus-based

Blood pressure threshold to initiate combination drug therapy in patients with diabetes and hypertension

When BP is more than 20/10 mmHg to 30/10 mmHg above goal, initiating therapy with two drugs, either as a separate prescription or in fixed dose combinations is recommended.

Note: For patients with diabetes and hypertension, the target blood pressure should be  $\leq 130/80$  mmHg. Consensus-based

<u>Initial Treatment of Diabetes and Hypertension in the Absence of Heart Failure or Known Coronary Heart Disease or Microalbuminuria</u>

For the treatment of diabetes and hypertension in the absence of heart failure, known coronary heart disease, or microalbuminuria, either a thiazide type diuretic or an ACE inhibitor is the preferred first-line drug. Combination therapy of hydrochlorothiazide/ACE inhibitors as first-line therapy is an option.

Consensus-based

## Step therapy in the treatment of diabetes and hypertension

- For two drugs: When a second drug is required for hypertension control, it should be either an ACE inhibitor or a diuretic.
- For three drugs: If blood pressure is not controlled on a thiazide-type diuretic in addition to an ACE inhibitor, then treatment with a thiazide-type diuretic, an ACE inhibitor AND a beta-blocker are recommended.

## Consensus-based

<u>Drug Therapy for Patients with Diabetes, Hypertension, and Microalbuminuria or Diabetic Nephropathy</u>

If a person with diabetes, hypertension, and microalbuminuria (or albuminuria) is intolerant to an ACE Inhibitor, then, in the absence of contraindications, it is recommended that an angiotensin receptor blocker (ARB) be substituted to prevent progression of renal disease. Consensus-based

## Target Blood Pressure For People With Diabetes And Hypertension

For patients with diabetes and hypertension, the target blood pressure should be  $\leq$ 130/80 mmHg.

Evidence-based (A): Diastolic blood pressure; Consensus-based: Systolic blood pressure

B. Drug Therapy for Microalbuminuria in Normotensive Patients

ACE Inhibitors should be used in normotensive patients with diabetes and microalbuminuria (or albuminuria). Evidence-based (A)

If a person is intolerant to an ACE Inhibitor, then, in the absence of contraindications, it is recommended that an ARB be substituted to prevent progression of renal disease.

Consensus-based

## C. Lipid Management in Patients with Diabetes

## Statin therapy: Aged 40 to 80 years

Statin Therapy is recommended for all patients aged 40 to 80 years with diabetes and total cholesterol (TC)  $\geq$ 135, regardless of baseline LDL.

Evidence-based (A)

Initiate statin therapy with at least lovastatin 40 mg daily.\* Consensus-based

Clinical judgment is advised when considering lipid-lowering medications in people with diabetes who are at a very low ten-year CAD risk (<7 to 10% as determined from the "10-Year CAD Risk (%) and Recommendations for Dyslipidemia Drug Treatment" tables; or no history of CVD and less than two cardiovascular risk factors)\*\*

Consensus-based

## Statin therapy: Age < 40 years

In patients with diabetes under age 40 who have no known CAD and who have two or more CV risk factors,\*\* treat with lipid lowering drug therapy. Alternatively, use the "10-Year CAD Risk (%) and Recommendations for Dyslipidemia Drug Treatment" tables to identify candidates for treatment with lipid-lowering drug therapy. Consensus-based

For patients under age 40 with diabetes and established CAD, treatment with a statin is recommended. Consensus-based

## Statin therapy: Age >80 years

For patients over age 80 with diabetes and no established CAD, while statins are generally recommended, shared decision-making is also recommended.

Consensus-based

For patients over age 80 with diabetes and established CAD, treatment with a statin is recommended.

Consensus-based

\* Lower doses recommended for patients at high risk for rhabdomyolysis.

\*\* Total cholesterol >200 mg/dL, high-density lipoprotein (HDL) cholesterol <40 mg/dL, hypertension, microalbuminuria, or current smoking.

## LDL Goals for Patients with Diabetes

- The LDL target for patients age 40 or greater with diabetes is LDL <100 mg/dL.
- For patients age 40 or older with diabetes and CAD, an LDL target <70 mg/dL is an option.

Note: In some people, an LDL <70 to 100 mg/dL may be difficult to achieve. In these cases, use clinical judgment to weigh the benefits and risks of intensifying drug therapy.

#### Consensus-based

D. Drug Therapy for the Primary and Secondary Prevention of Cardiovascular Disease (CVD) Events in Patients with Diabetes

# ACE Inhibitor Therapy for Primary and Secondary Prevention of CVD in Diabetes

ACE inhibitors should be prescribed to patients with diabetes age  $\geq$ 55 years with one or more cardiovascular factors (Total cholesterol >200 mg/dL, HDL cholesterol <40 mg/dL, hypertension, microalbuminuria, or current smoking) or a history of CVD (CAD, stroke, or peripheral vascular disease).

Evidence-based (B)

## Aspirin Therapy in Diabetes for Prevention of CVD

Patients with diabetes  $\geq$ 40 years old should be treated with at least 81 mg/day aspirin unless contraindicated. People with aspirin allergy, bleeding tendency, recent gastrointestinal bleeding, age >85, and clinically active hepatic disease are not candidates for aspirin therapy. Consensus-based

## Beta-Blocker Therapy for Secondary Prevention of CVD in Diabetes

Beta-blockers are recommended for patients with diabetes with a history of MI.

Evidence-based (A)

Beta-blockers are an option for secondary prevention of CVD without MI in patients with diabetes.

Consensus-based

<u>Multifactorial Interventions for Preventing CVD in Patients with Diabetes</u>

Concurrent treatment of cardiovascular (CV) risk factors is recommended for the prevention of cardiovascular events in patients with type 2 diabetes.

Consensus-based

## E. Management of Glucose

## Glucose Control

Intensive glucose control is recommended in patients with diabetes, if not contraindicated.

Evidence-based (A)

# <u>Initial Drug Therapy for Glucose Lowering in Type 2 Diabetes</u>

Metformin is recommended as the first-line glucose lowering drug in overweight patients with type 2 diabetes. Evidence-based (B)

## Medical Step Therapy for Glucose Control

- Following failure to achieve goals on monotherapy, more than one medication is recommended.
- There is insufficient evidence to recommend an optimal medication combination for type 2 diabetes not controlled with a single agent.

Consensus-based

## Target Blood Glucose

The overall treatment goal for HbA1c is <7%.

The HbA1c goal should be individualized based on shared decision-making.

- Patients with comorbid diseases, older adults, and patients with unusual conditions may need less stringent treatment goals.
- Conversely, more stringent goals are an option in individual patients.

## Consensus-based

# F. Monitoring Microalbumin in Patients on ACE Inhibitors with Documented Microalbuminuria

Continued monitoring of microalbumin is optional in people with diabetes and established microalbuminuria, who are on an ACE Inhibitor or ARB.

Consensus-based

# G. Screening for Retinopathy

Diabetes patients with background retinopathy or more severe disease should be monitored at least annually, and those without retinopathy should be screened every one to two years.

Consensus-based

## H. Foot Screening

All patients with diabetes should have a foot screening that includes a monofilament test. Patients with an abnormal monofilament test are at a high risk for lower limb complications and are candidates for entry into a podiatry population-based foot care program, or equivalent. Consensus-based

Annual foot screening is recommended for patients with diabetes. Consensus-based

## IV. Self-Management

I. Diabetes Self-Management Education

Patient training in self-care behaviors is recommended as a component of any diabetes management program.

Evidence-based (A): Effect on glucose control; Consensus-based: Effect on other outcomes

J. Self-Monitoring of Blood Glucose (Type 1 and Type 2 Diabetes)

Patients with type 1 and 2 diabetes should monitor their blood glucose. When self-monitoring of blood glucose (SMBG) is used, results should be accompanied by an appropriate adjustment in therapy.

Evidence-based (A): Type 1 Diabetes; Consensus-based: Type 2 Diabetes

## **Definitions**:

Recommendations are classified as either "evidence-based (A-D, I)" or "consensus." Refer to the table below for full definitions.

- Evidence-based: sufficient number of high-quality studies from which to draw a conclusion, and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered "evidence-based" if there is insufficient evidence and no practice is recommended.
- Consensus: insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team.

Label and Language of Recommendations\*

| Label | Evidence-Based Recommendations |
|-------|--------------------------------|

| Label                  | Evidence-Based Recommendations  |
|------------------------|---|
| Evidence-<br>based (A) | Language: <sup>a</sup> The intervention is strongly recommended for eligible patients.  |
|                        | Evidence: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs.   |
|                        | Evidence Grade: Good.   |
| Evidence-<br>based (B) | Language: <sup>a</sup> The intervention is recommended for eligible patients.   |
|                        | Evidence: The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs.  |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (C) | Language: <sup>a</sup> No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.)  |
|                        | Evidence: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (D) | Language: <sup>a</sup> Recommendation against routinely providing the intervention to eligible patients.  |
|                        | Evidence: The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits.  |
|                        | Evidence Grade: Good or Fair.   |
| Evidence-<br>based (I) | Language: <sup>a</sup> The evidence is insufficient to recommend for or against routinely providing the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.)   |
|                        | Evidence: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.   |
|                        | Evidence Grade: Insufficient.   |
| Consensus-<br>based    | Language: <sup>a</sup> The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline  |

| Label | Evidence-Based Recommendations  |
|-------|---|
|       | Directors.  |
|       | Evidence: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. |
|       | Evidence Grade: Insufficient, unless otherwise stated.  |

For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the evidence were good or fair, the recommendation would usually be evidence-based. In this kind of consensus-based recommendation, the evidence grade should point this out, e.g., "Evidence Grade: Good, supporting a different recommendation."

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

Appropriate prevention, treatment, and management diabetes

#### POTENTIAL HARMS

- Side effects of medications
- Anxiety, inconvenience, and possible inaccuracies associated with tests (microalbuminuria testing, retinopathy screening, foot screening)
- Decreased quality of life associated with self-monitoring of blood glucose

<sup>[</sup>a] All statements specify the population for which the recommendation is intended.

<sup>\*</sup> Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

# CONTRAINDICATIONS

## **CONTRAINDICATIONS**

Contraindications for aspirin include aspirin allergy, bleeding tendency, recent gastrointestinal bleeding, age >85, and clinically active hepatic disease

## QUALIFYING STATEMENTS

#### **QUALIFYING STATEMENTS**

- These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis.
- Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente Care Management Institute. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente Care Management Institute; 2005 Dec. 206 p. [127 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Mar (revised 2006)

## GUI DELI NE DEVELOPER(S)

Kaiser Permanente Care Management Institute - Managed Care Organization

## SOURCE(S) OF FUNDING

Kaiser Permanente Care Management Institute

## **GUIDELINE COMMITTEE**

Kaiser Permanente Diabetes Guidelines Project Management Team Kaiser Permanente Adult Diabetes Guideline Development Team

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Kaiser Permanente Care Management Institute. Adult diabetes clinical practice guidelines. Oakland (CA): Kaiser Permanente Care Management Institute; 2004 Mar. 167 p.

To keep current with changing medical practices, all guidelines are reviewed, and if appropriate, revised at least every two years.

#### GUIDFLINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16<sup>th</sup> Floor, Oakland, CA 94612

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Kaiser Permanente Care Management Institute. Guidelines for the management of adult diabetes in Primary Care. Oakland (CA): Kaiser Permanente Care Management Institute; 2006. 10 p.

Electronic copies: Not available at this time.

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16<sup>th</sup> Floor, Oakland, CA 94612

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on September 15, 2004. The information was verified by the guideline developer on September 16, 2004. This NGC summary was updated by ECRI on September 28, 2006. The updated information was verified by the guideline developer on October 30, 2006.

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